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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,221

07/27/2005

Christopher Robin Lowe

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

NOTIFICATION DATE

DELIVERY MODE

03/17/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Office Action Summary	Application No. 10/520,221	Applicant(s) LOWE ET AL.	
	Examiner Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Response and amendment filed 06 January 2010 to the Office Action mailed 08 September 2009 is acknowledged and entered.

Informal Matters

2. Please note for the record that Mr. Ralph Gitomer's title as the Supervisory Examiner in the remarks filed 06 January 2010 (See Page 4, Line 15) is incorrect. Currently, Mr. Gitomer is a Primary Examiner in Art Unit 1657. Appropriate correction to the record is in order and will be appreciated.

Claims Status

3. Claims 6-7, 9 and 14 have been cancelled.
4. Claims 1-2 and 8 have been amended.
5. Claims 1-5, 8 and 10-13 are currently pending and are examined on merits.

Withdrawals

6. In view of Amendments and remarks filed 06 January 2010, the following objections and rejections in the Office Action mailed 08 September 2009 are hereby withdrawn:

- Lack of sufficient antecedent basis for indefiniteness to Claim 2 under 35 U.S.C. § 1112, 2nd paragraph;
- Anticipatory/obviousness rejection of Claims 1-5 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Bruno et al. (1996. Immunomagnetic-Electrochemiluminescent Detection of *Bacillus anthracis* Spores in Soil Matrices. Applied and Environmental Microbiology, Volume. 62, Number 9, Pages 3474-3476) and
- Obviousness rejection to Claims 1-5, 8 and 10-13 under 35 U.S.C. § 103(a) as being unpatentable over Bruno et al. (1996. Immunomagnetic-Electrochemiluminescent Detection of *Bacillus anthracis* Spores in Soil Matrices. Applied and Environmental Microbiology, Volume. 62, No. 9, Pages 3474-3476) in view of Walt et al (US 6,377,721 B I), and Weimer et al (US 6,399,317, issued 4 June 2002).

Claim Objections

7. Claims 1 and 8 are objected to as follows:

- ▲ the phrase, “cell’s metabolism, growth and/or germination” because a biological cell by definition does not germinate, it grows or multiplies by division. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. In view of the amendment filed 06 January 2010, the following is a new rejection under 35 U.S.C. § 112, 2nd paragraph.

10. Claims 8 and 10-13 are rejected under 35 U.S.C. § 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- Claim 8 as currently presented is very confusing, in comprehensible unclear and vague because it is not clear whether the method for which said device is applicable entails immobilizing a cell and/or detecting a cell? Furthermore, it is also not clear where the cell and or antibody is immobilized. It is also not clear where each of sensor, antibody, or other components of said device are located and the respective functionality of each of the device components. Appropriate correction/ explanation is required.

Claims 10-13 depend directly from the rejected claim 8 and are, therefore, also rejected under 35 U.S.C. § 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 103

11. In view of the amendment filed 06 January 2010, the following is a new rejection under 35 U.S.C. § 103(a).

12. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

14. Claims 1-5, 8 and 10-12 are rejected under 35 U.S.C. 103(a) as being obvious over combined teachings from Weimer et al (US 6,399,317, issued 4 June 2002) in view of Bruno et al. (1996. Immunomagnetic-Electrochemiluminescent Detection of *Bacillus anthracis* Spores in Soil Matrices. Applied and Environmental Microbiology, Volume. 62, No. 9, Pages 3474-3476) and Lowe et al (U.S. Patent 5,989,923 A)

Claims 1-5, 8 and 10-12 are drawn to a method to identify a cell or metabolites thereof, wherein the cell is immobilized to an antibody and is also in a device containing a sensor, a growth medium addition step, wherein said sensor is holographic, sensitive to a product of cell's growth and detects changes in an optical characteristic of said sensor. Claims also describe a device to detect cells, wherein said device comprises a series of chambers, a holographic sensor, an antibody, and a growth medium and an inlet for the sample. The antibody is immobilized on a wall of a chamber and said antibody is immobilized on a magnetic particle.

Regarding Claims 1-5, 8 and 10-12, Weimer et al., teach a device for detecting bacteria. The device contains beads which are coated with an antibody specific for a type of bacteria, e.g., *Bacillus subtilis* and *Bacillus globigii* (See Table 1 and Examples 15-16); the antibodies raised against said bacteria (e.g., *Bacillus stearothermophilus* and *Bacillus subtilis* (Example 2)) are immobilized on magnetic beads (Examples 4-8) and said beads applied to capture said bacteria as exemplified by *Bacillus stearothermophilus* (Example 11). Weimer et al., further teach, a sample suspected of containing bacteria is added through an inlet port, and allowed to flow through a chamber containing the beads. The beads then selectively accumulate bacteria from the liquid sample (see Column 3, Line 40 to Column 4, Line 19; Column 6, Lines 13-21, as examples). The bacteria can also be subsequently washed while bound to

the magnetic beads by addition of a wash buffer (see Example 13, for example). Weimer et al., also teach that bacterial spores can be used to generate antibodies in mice. These antibodies can also be attached to beads, and will effectively capture spores in the chamber discussed above (see Examples 2, 3; and 13). Weimer et al., are silent regarding a growth medium and a holographic sensor.

Bruno et al., teach detection of anthrax spores in soil suspensions through an immunomagnetic electrochemiluminescence method, wherein anthrax spores in the range of $0-10^6$ were detected. Bruno et al., further teach immobilizing the spores to a spore-specific antibody, wherein said antibody is attached to biotinylated Dynal magnetic beads. After addition of target samples to said beads, the sample+ beads mixture was treated with ruthenium-labeled Gt reporter antiserum, the samples were analyzed on an ORIGIN analyzer to detect the photon counts Abstract; Page 3474, Column , Lines 18-35). Bruno et al., additionally teach detection of said spores in a soil sample. Note since the spore sample also contained soil suspension, the sample was added with a growth medium because soil extract/suspension is an art-known microbiological culture medium. Furthermore, the spore is a product of cellular metabolism because spore is produced by the vegetative cell to sustain the unsuitable environmental/culture conditions for cell viability.

Lowe et al teach a biological sensor comprised of a holographic detector and a hologram, wherein said hologram is supported on or within a holographic support medium, is reactive with a substance disposed throughout said medium, or a specific binding conjugate within the medium. Furthermore a specific variation within the medium causes one or more optical characteristics of the hologram (Abstract, Lines 1-12). Said hologram/sensor measures analytes. In particular the sensor has applications in detecting biologically secreted proteins, or proteases (Column 6, Lines 63-68), or antigen-antibody (Column 8, Line 40). The sensitivity and detection of an analyte in said sensor is facilitated by any binding system, wherein either partner is incorporated into the holographic support medium and the other one is analyte (Column 8, Lines 34-45). Lowe et al., further teach that the sensor is capable of detecting bacteria, for example (Column 11, lines 18-46, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to combine/substitute the teachings from Weimer et al., with those of Bruno et al., and Lowe et al., to detect bacterial cells by trapping them on beads with antibodies and detect their presence by means of a holographic sensor; because Bruno et al., teach that bacteria can be trapped on magnetic beads by means of antibodies and that they can subsequently be cultured in liquid media and Lowe et al., teach detection of bacterial sensors by applying a holographic sensor, wherein said holographic sensor analyses

for the proteases of bacterial metabolism. Please note, protease is produced as function of cellular metabolism that can be detected with a hologram. Furthermore, teachings from each one of Weimer et al., Bruno et al., and Lowe et al., are to detect/identify a product (either bacterial spores or an enzyme) of cellular metabolism wherein the technique/device of Weimer et al., could be substituted with the holographic sensor of Walt et al., or the holographic sensor that Lowe et al., teach. Furthermore, said products of cellular metabolism are identified by recognizing an optical property, or fluorescence detection (Weimer et al).

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to combine/substitute the teachings from Weimer et al., with those of Bruno et al., and Lowe et al., to provide a device in which one can capture bacteria through antibody-antigen reaction on immunomagnetic beads coated with anti bodies to which bacteria are immobilized, provide them a growth medium, and observe their metabolism via optical interrogation with a holographic sensor; because each of the above-cited references teach a method to identify a product of cellular metabolism indicating presence of a cell, wherein Bruno et al., remedy the deficiency in Weimer et al's teachings of a bacterial growth/ culture medium, and Lowe et al., remedy the deficiency of a holographic sensor to detect the presence of a cellular metabolite/bacterium in Weimer et al's teachings.

From the teachings of the reference cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. Claim 13 is rejected under 35 U.S.C. §103 (a) as obvious over combined teachings from Weimer et al (US 6,399,317, issued 4 June 2002) in view of Bruno et al. (1996. Immunomagnetic-Electrochemiluminescent Detection of *Bacillus anthracis* Spores in Soil Matrices. Applied and Environmental Microbiology, Volume. 62, No. 9, Pages 3474-3476) and Lowe et al (U.S. Patent 5,989,923 A) as applied to Claims 1-5, 8 and 10-12 and further in view of Walt et al (US 6,377,721 B 1)

Claim 13 recites a device to detect cells, wherein said device additionally comprises a series of chambers.

Regarding Claim 13, teachings from teachings from Weimer et al (US 6,399,317, issued 4 June 2002) in view of Bruno et al. (1996. Immunomagnetic-Electrochemiluminescent Detection of *Bacillus anthracis* Spores in Soil Matrices. Applied and Environmental Microbiology, Volume. 62, No. 9, Pages

3474-3476) and Lowe et al (U.S. Patent 5,989,923 A) have been discussed in item 14 *supra*. Weimer et al., however, are silent regarding a holographic sensor device comprising chambers.

Walt et al., teach multiple chambers in a single device (see Abstract for example) and further teach that the cells can be immobilized by immunophilic and magnetic means (see Column 12, lines 55-64, for example), and that cell metabolism can be monitored by provision of a fluorescent metabolite, that fluorophores responsive to the metabolite can be activated by excitation light, and resulting fluorescence can be detected by fiber optics (See, Column 15, Lines 48-54, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to combine/substitute the teachings from Weimer et al., with those of Bruno et al., and Lowe et al., and further the teachings from Walt et al., to detect bacterial cells by trapping them on beads with antibodies and detect their presence by means of a holographic sensor; because Bruno et al., teach that bacteria can be trapped on magnetic beads by means of antibodies and that they can subsequently be cultured in liquid media, Lowe et al., teach detection of bacterial sensors by applying a holographic sensor, wherein said holographic sensor analyses for the proteases of bacterial metabolism. and Walt et al., teach multiple chambers in a single device (see Abstract for example) and Walt et al., further teach that the cells can be immobilized by immunophilic and magnetic means, and that cell metabolism can be monitored by provision of a fluorescent metabolite, that fluorophores responsive to the metabolite can be activated by excitation light, and resulting fluorescence can be detected by fiber optics. Please note, fluorescence is an optical property.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant invention was made to combine/substitute the teachings from Weimer et al., with those of Bruno et al., Lowe et al., and Walt et al., to provide a device in which one can capture bacteria through antibody-antigen reaction on immunomagnetic beads coated with anti bodies to which bacteria are immobilized, provide them a growth medium, and observe their metabolism via optical interrogation with a holographic sensor; because each of the above-cited references teach a method to identify a product of cellular metabolism indicating presence of a cell, wherein Bruno et al., remedy the deficiency in Weimer et al's teachings of a bacterial growth/ culture medium, Lowe et al., remedy the deficiency of a holographic sensor to detect the presence of a cellular metabolite/bacterium in Weimer et al's teachings and Walt et al., remedy the teachings of Weimer et al., for the absence of multi-chambered holographic sensor, wherein cells can be immobilized by immunophilic and magnetic means, and that cell metabolism

can be monitored by provision of a fluorescent metabolite, that fluorophores responsive to the metabolite can be activated by excitation light, and resulting fluorescence can be detected by fiber optics.

From the teachings of the reference cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

16. Applicants' amendment filed 06 January 2010 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. For the aforementioned reasons, no claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for

unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Examiner, Art Unit 1657

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09 March 2010

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